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Doctors Laboratory, Inc.
2906 Julia Drive
Valdosta, GA 31602
October 9, 2001

Mr. Robert L. Stephenson II
Division of Workplace Programs
CSAP
5600 Fishers Lane
Rockwell II, Suite 815
Rockville, MD 20857

Dear Mr. Stephenson,

I have reviewed the proposed revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs.

I noted an inconsistency that needs to be addressed. On page 43879, it was proposed to take out the less than or equal to when addressing specific gravity, but in discussing substituted specimens on the next page, the criteria for a substituted specimen is said to be less than 1.002 or greater than or *equal to* 1.020. Why not call it greater than 1.019?

I also have questions about the use of a second technology for adulterants. I don't think there are many conveniently applied second technologies for nitrite, chromate, bleach, soap, or gluteraldehyde. Nor do I think that most of the methods in use are in the category of reference methods. I think that the state of the art for these analytes is a method that is validated with documentation of linearity, precision and accuracy.

Another problem that I have with the proposed revisions is the definition of the calibrators and controls that are to be used with dilute and substituted specimens for creatinine and specific gravity.

The proposed revisions state that the creatinine must be calibrated at 5.0 or 20.0 mg/dL and that controls must be run in the ranges of 2-4, 6-8,5-20, and 21-25. This is in addition to the controls that I normally run at 30 and 60 mg/dL. This requirement is excessive. My creatinine procedure is calibrated at 100 mg/dL and has documented linearity from 3.9 to 500 mg/dL. I also have precision data to demonstrate that the coefficient of variation is 2 percent in the range from 5 (plus or minus 0.1 mg/dL) to 20 mg/dL (plus or minus 0.4 mg/dL). To require that a specific concentration be run for calibration and to further require sandwiching the decision levels is excessive and prohibitively expensive to be applied on a routine basis.

Similarly, the procedure for specific gravity requires calibration at 1.000 and controls at 1.001, 1.002-1.010,1.015-1.020, and 1.020-1.025. The refractometer in use in our laboratory is NIST traceable and produces a gravity of 1.000 for deionized water. According to the manufacturer, if I adjust the specific gravity of deionized water, I destroy the NIST traceability, and it is more likely that there is a problem with the water if I fail to obtain a result of 1.000. In other words, the refractometer is calibrated with those standards that the manufacturer finds suitable to produce traceability to NIST. If the refractometer fails to produce an acceptable result for water, the refractometer is probably broken (*i.e.* dropped). *We do not calibrate the refractometer.* Further, specific

gravity as determined by refractometer is a physical property. As such, a single control demonstrates that the refractometer is functioning properly. Numerous controls are not required. Again, we have linearity data from 1.0000 to 1.0276 and precision data around the cutoffs. Again, it is unreasonable to require numerous controls sandwiching the decision levels.

The same is true for nitrites, pH, chromate, gluteraldehyde, and soap. If the laboratory has linearity and precision data, it is not necessary to sandwich all of the decision levels.

Sincerely,

David C. Williams, Ph. D.